Therefore, notice is given to Agri-Tech, Inc., and to all other interested persons who may be adversely affected, that the Director, CVM, proposes to issue an order under section 512(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(e)) withdrawing approval of NADA 13–502 and all amendments and supplements thereto on the ground that the applicant has failed to submit the reports required under § 510.300. Upon withdrawal of NADA 13–502, the corresponding regulation (21 CFR 520.1157) will be revoked.

In accordance with the provisions of section 512 of the act and regulations issued under it (parts 510 and 514 (21 CFR parts 510 and 514)), and under authority delegated to the Director, CVM (§ 5.84 (21 CFR 5.84)), CVM hereby provides the applicant an opportunity for a hearing to show why approval of the NADA and all amendments and supplements thereto should not be withdrawn (and the corresponding regulations revoked) and an opportunity to raise, for administrative determination, all issues relating to the legal status of the application and drug products approved thereunder. Any hearing would be subject to the provisions of 21 CFR part 12.

An applicant who decides to seek a hearing shall file on or before December 20, 1996, a written notice of appearance, request for a hearing, and the data, information, and analyses relied on to justify a hearing as specified in § 514.200.

Procedures and requirements governing this notice of opportunity for a hearing, notice of appearance and request for hearing, submission of information and analysis to justify a hearing, other comments, and a grant or denial of a hearing, are contained in § 514.200.

The failure of an applicant to file a timely, written notice of appearance and request for a hearing as required by § 514.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposed action and constitutes a waiver of any contentions about the legal status of the product. In such case, the Director, CVM, under the authority delegated to him in § 5.84(a)(2), will, without further notice, enter a final order withdrawing approval of the application. Thereafter, the product may not be legally marketed, and CVM may begin appropriate regulatory action to remove it from the market. Any new animal drug product which is not the subject of an approved application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that justifies a hearing. Reports submitted to remedy the deficiencies must be complete in all respects as required by § 510.300. If it is clear that the reports submitted are not complete or that there is no genuine and substantial issue of fact that precludes the withdrawal of approval, or that the request for a hearing is not made in the required format or with the required analysis, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing. If a hearing is requested and is justified by the sponsor's response to this notice, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will begin will be issued.

All submissions pursuant to this notice shall be filed in two copies. Except for information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512(e) (21 U.S.C. 360b(e))) and under authority delegated to the Director, CVM (§ 5.84).

Dated: October 18, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–29630 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0382]

Milwhite, Inc.; Filing of Food Additive Petition (Animal Use) Hydrated Sodium Calcium Aluminosilicate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Milwhite, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of hydrated sodium calcium aluminosilicate as a binder for aflatoxins in feeds.

DATES: Written comments on the petitioner's environmental assessment by January 21, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Henry E. Ekperigin, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2230) has been filed by Milwhite, Inc., 7050 Portwest Dr., suite 190, Houston, TX 77024. The petition proposes to amend the food additive regulations in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of hydrated sodium calcium aluminosilicate as a binder for aflatoxins in feeds.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before January 21, 1997 submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's findings of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: November 1, 1996.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 96–29632 Filed 11–19–96; 8:45 am]

BILLING CODE 4160–01–F